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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/926,005 | 11/02/2001 | Masatoshi Noda | 010969 | 5152 |

7590 05/21/2002

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[REDACTED] EXAMINER

KRISHNAN, GANAPATHY

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1623

DATE MAILED: 05/21/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

09/926,005

Applicant(s)

NODA ET AL.

Examiner

Art Unit

Ganapathy Krishnan

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

4) Claim(s) 1-11 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-11 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Disposition of Claims

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) Interview Summary (PTO-413) Paper No(s) _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under U.S.C. 102(b) as being anticipated by Nafisi-Movaghah et al (USPN 5912363).

Claims 1-3 are drawn to proanthocyanidin obtained from edible plant or an edible plant derived material, wherein the edible plant-derived material is an apple or grape.

Nafisi-Movaghah et al teach (abstract; column 9, examples 1-3) the isolation of proanthocyanidins from grape seeds. This disclosure renders the instantly claimed proanthocyanidin compounds anticipated.

Claims 6-8 are rejected under U.S.C. 102(b) as being anticipated by Ariga et al (USPN 4797421).

Claims 6-8 are drawn to compositions comprising proanthocyanidin.

Ariga et al teach (col. 13-22, claims 1-4) compositions containing proanthocyanidins. These compositions anticipate the compositions of claims 6-8.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of enterotoxin type bacterial infectious diseases, does not reasonably provide enablement for prevention of enterotoxin type bacterial infectious diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

- (A) The breadth of claims
- (B) The state of the prior art
- (C) The amount of direction provided by the inventor
- (D) The existence of working examples and
- (E) The quantity of experimentation needed to make or use the invention based on the content of the disclosure

The breadth of the claims

Claims 6-8 are drawn to compositions for the treatment and /or prevention of diphtheria, pertussis, tetanus and opportunistic infection comprising as an effective ingredient proanthocyanidin, treatment and/or prevention of enterotoxin type bacterial infectious disease and treatment and/or prevention of cholera, botulinus and diarrhea.

The scope of the claims is seen to include the administration of proanthocyanidin to a healthy person, and the subsequent exposure to conditions which would cause the said diseases, wherein the said compound prevents said exposure from manifesting itself in the subject exposed.

The state of the prior art

The prior art cited by the applicants disclose treatment for bacterial infections. However, there is no disclosure of potential bacterial infection preventive activity of the compounds seen in the prior art. The prior art appears to be silent with regard to preventive procedures recognized by skilled artisans in the field.

The amount of direction provided by the inventors

The instant specification is not seen to provide enough guidance that would allow a skilled artisan to extrapolate from the disclosure and the examples provided to enable the use of the said compounds to prevent the said bacterial infectious diseases. The specification also fails to direct the skilled artisan in correlative prior art procedures which might provide the basis for an advance in treating the said diseases which induces prevention of the said diseases.

The existence of working examples

The working example set forth in the instant specification is drawn to data involving rat. The skilled artisan in this field would not extrapolate the preventive efficacy of the compounds claimed or the use of the same in preventive methods from just this example provided. The disclosure does not show the prevention of the said diseases.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to enable prevention of the said diseases with the compounds set forth in the claims. A skilled artisan would not extrapolate the preventive efficacy from the results disclosed for the examples in rats, set forth in the instant specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5, 9,10, and 11are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4, 5, 9,10 and 11 are drawn to an ADP-ribosylation inhibitor wherein proanthocyanidin is extracted with at least one solvent, the proanthocyanidin is purified by adsorption on an anionic exchange resin, a composition for the treatment and/or prevention of enterotoxin type bacterial infectious disease, extraction of proanthocyanidin with a solvent and purification of the proanthocyanidin.

Claim 4 recites extraction of proanthocyanidin with at least one solvent selected from water, an alcohol, an ester and a ketone. The word ‘and’ after ester in the claim renders the claim indefinite. It is not clear whether the applicants mean one solvent selected from water, an alcohol, an ester in combination with a ketone, or just the ester and a ketone combination, or they mean at least one solvent selected from water, an alcohol, an ester or a ketone.

Claims 5 and 11 recite the purification of proanthocyanidin using a styrene type adsorption resin, an anionic exchange resin, an octadecyl-chemically binding type silica gel, an octyl-chemically binding type silica gel, a phenyl chemically binding type silica gel and silica gel. The term "type" in claims 5 and 11 is a relative term that renders the claims indefinite. The term "type" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. It is also not clear if all of these resins and gels should be used in succession in the purification process or just one of them is enough. The claim also ends with "and a silica gel." It is not clear if silica gel should be used in combination with any of the other resins and gels mentioned in the claim or silica gel is one of the adsorption gels to be used by itself in the purification process.

Claim 10 recites the treatment and/or prevention of enterotoxin type bacterial infectious disease wherein proanthocyanidin is the one extracted with at least at least one solvent selected from water, an alcohol, an ester and a ketone. The claim ends with "and a ketone". This makes it unclear whether the ketone should be used in combination with water an alcohol and an ester or it is one of the solvents that could be used by itself, or if the ester and ketone are used in combination.

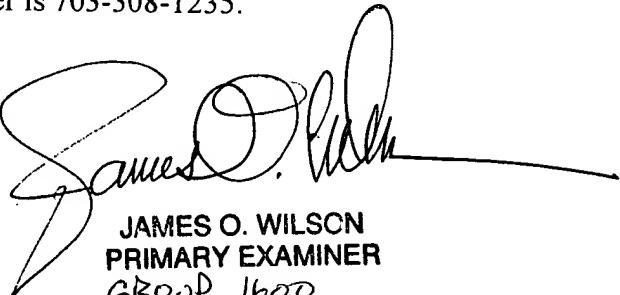
Claim 9 recites the limitation "said edible plant or edible plant-derived material". There is insufficient antecedent basis for this limitation in the claim. Claim 9 depends on claim 7 which (claim 7) does not recite edible plant or edible plant-derived material in the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 703-305-4837. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

GK
May 17, 2002



JAMES O. WILSON
PRIMARY EXAMINER
GROUP 1600